

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

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AUTHORITY: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 958.

SOURCE: 60 FR 32454, June 22, 1995, unless otherwise noted.

GENERAL INFORMATION

§ 1309.01 Scope of part 1309.

Procedures governing the registration of manufacturers, distributors, importers and exporters of List I chemicals pursuant to Sections 102, 302, 303, 1007 and 1008 of the Act (21 U.S.C. 802, 822, 823, 957 and 958) are set forth generally by those sections and specifically by the sections of this part.

§ 1309.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1309.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

[75 FR 10680, Mar. 9, 2010]

FEEs FOR REGISTRATION AND REREGISTRATION

§ 1309.11 Fee amounts.

(a) For each application for registration or reregistration to manufacture the applicant shall pay an annual fee of \$2,293.

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(b) For each application for registration or reregistration to distribute, import, or export a List I chemical, the applicant shall pay an annual fee of \$1,147.

[75 FR 4980, Feb. 1, 2010]

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture, distribute, import, or export, the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) Payments should be made in the form of a credit card; a personal, certified, or cashier's check; or a money order made payable to "Drug Enforcement Administration." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

[75 FR 4980, Feb. 1, 2010]

REQUIREMENTS FOR REGISTRATION

§ 1309.21 Persons required to register.

(a) Unless exempted by law or under §§ 1309.24 through 1309.26 or §§ 1310.12

through 1310.13 of this chapter, the following persons must annually obtain a registration specific to the List I chemicals to be handled:

(1) Every person who manufactures or imports or proposes to manufacture or import a List I chemical or a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) Every person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under § 1300.02(b)(28)(i)(D) of this chapter.

(b) Only persons actually engaged in the activities are required to obtain a registration; related or affiliated persons who are not engaged in the activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(c) The registration requirements are summarized in the following table:

SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS

Business activity	Chemicals	DEA forms	Application fee	Registration period (years)	Coincident activities allowed
Manufacturing	List I, Drug products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510 Renewal—510a	\$2,293 2,293	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
Distributing	List I, Scheduled listed chemical products.	New—510 Renewal—510a	1,147 1,147	1	
Importing	List I, Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510 Renewal—510a	1,147 1,147	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
Exporting	List I, Scheduled listed chemical products.	New—510 Renewal—510a	1,147 1,147	1	